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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,241	12/13/2001	Roland Horres	49276-262679	1968

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EXAMINER

GILPIN, CRYSTAL M

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 02/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary

Application No.

09/914,241

Applicant(s)

HORRES ET AL.

Examiner

Crystal M Gilpin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-19 and 21-28 is/are rejected.
- 7) ☒ Claim(s) 16 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4 and 9</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 16 is objected to because of the following informalities: In order to avoid a 101 rejection it is suggested that applicant restate claim 16 as (changes in *italic*) – wherein the hemocompatible surface comprises a surface *extracted from* an animal organ, an animal organ part...- . (See MPEP 2105)

Appropriate correction is required.

2. Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 17 is rejected as being indefinite because the language as written is confusing.

It is suggested to rewrite the claim with fewer “or” statements in order to clearly define the list of potential materials.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 15-17, 21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bruchman (WO 95/29712).

Regarding claim 15, Bruchman discloses a synthetic base material with a layer of cells, constituting the hemocompatible surface, and an extracellular matrix (Figure 4), constituting a constituent of an outer layer of a mesothelial cell (Page 16, Line 13).

Regarding claim 16, Bruchman discloses that the hemocompatible surface could include cells from a xenogenic source on its surface (Page 6, Line 9).

Regarding claim 17, Bruchman discloses that the cells of the hemocompatible surface could be mesothelial cells (Page 16, lines 9-14).

Regarding claim 21, Bruchman discloses that the hemocompatible surface is substantially non-thrombogenic (Page 20, Line 20-23).

Regarding claim 23, Bruchman discloses that an article such as a heart valve (Fig. 9) comprises the hemocompatible surface.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruchman (WO 95/29712) in view of Minuth (USPN 6,187,053).

Regarding claims 22 and 23 Bruchman discloses a hemocompatible surface, but lacks the

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teaching of the surface comprising metal or an article or device. Minuth teaches of a hemocompatible surface or porous carrier that is made of metal so that it has the strength to be shaped in the form of an implant. (i.e. hip joint- Figure 1 and 3), comprising an article or device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Bruchman to have the hemocompatible surface made of metal to provide a strong implantable device.

6. Claims 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al. (USPN 6,071,973) in view of Bruchman (WO95/29712).

Regarding claim 24, 25 and 26, Keller et al. teach of binding a biological inert endothelial cell surface polysaccharide to a biopolymer, where the biopolymer is a hemocompatible surface (Column 1, Lines 7-14). Keller et al. lack the teaching of the process of isolating the cell constituent (polysaccharide) from the outer layer of a mesothelial cell. Bruchman teaches of a hemocompatible surface where the cells used for the surface are mesothelial cells. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to obtain the polysaccharide material by isolating it from the outer layer of a cell of whole blood or a cell fraction, such as a mesothelial cell, erythrocyte, leucocyte or thrombocyte, to provide an anti-coagulation surface.

Regarding claim 28, Keller et al. teach that the endothelial cell polysaccharide is immobilized on the hemocompatible surface (Column 1, Line 66 – Column 2, Line 5).

7. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruchman (WO 95/29712) in view of Hubbell et al. (USPN 6,156,572).

Regarding claims 18 and 19, Bruchman teaches of a hemocompatible surface with an extracellular matrix material incorporated on it, however Bruchman lacks the teaching of the matrix containing specific molecules. Hubbell et al. teach of a bio-artificial extracellular matrix that can be implanted as a hemocompatible surface for tissue regeneration (Column 6, Lines 56-68). Hubbell et al. further teach that the extracellular matrix includes molecules such as heparan sulfate and chondroitin sulfate (Column 1, Lines 26-41) to serve as a biological glue. It is inherent that the heparan sulfate would be obtained from an erythrocyte plasma membrane. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Bruchman to include heparan sulfate or chondroitin sulfate molecules in the extracellular matrix to provide adhesion within the material.

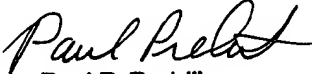
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Crystal M Gilpin whose telephone number is 703-305-8122. The examiner can normally be reached on M-F, 9:00-5:00 (Second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The group fax phone number for the organization where this application or proceeding is assigned are 703-305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

cmg
February 5, 2003


Paul B. Prebilic
Primary Examiner